EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Director-General

Brussels,
SANCO.B2[redacted]

NOTE TO COMMISSIONER BORG

Subject: **Draft reports of the European Parliament on the Proposal for a Regulation on medical devices and the Proposal for a Regulation on *in vitro* diagnostic medical devices**

The Commission's Proposals for a Regulation on medical devices and for a Regulation on *in vitro* diagnostic medical devices were adopted on 26 September 2012 and are currently discussed in the European Parliament and the Council. The draft reports of the Rapporteurs in the ENVI Committee (lead committee) and the draft opinions of the Rapporteurs in the IMCO and EMPL Committees (associated committees) are now available and will be discussed at the Parliament on 23, 24 and 25 April 2013. The purpose of this note is to inform you of the most salient points and request your approval on the position to take.

1. Proposal on medical devices

There are **two important issues which are treated in the reports of the Rapporteurs of the ENVI and IMCO Committees**: the system for approval of medical devices and the reprocessing of single-use devices. The other issues are specific to each report.

- **The system for approval of medical devices**

The Commission proposes to continue to build on the current system of conformity assessment of medical devices by notified bodies, while reinforcing it for high risk devices by empowering Member States Competent Authorities, through the Medical Device Coordination Group (MDCG) to have a 'second look' at some individual conformity assessments, before they are made available on the Union market, through a new scrutiny procedure.

ENVI Committee:

The Rapporteur proposes that medical devices implanted into the body (*e.g.* breast or hip implants), incorporating a substance considered to be a medicinal product (*e.g.* drug-eluting stents), intended to administer a medicinal product (*e.g.* insulin pumps), or utilising non-viable tissues or cells of human or animal origin or their derivatives (*e.g.* collagen) should be subject to a **marketing authorisation procedure,** at **centralised level** (EMA) for devices of an **innovative** nature and at **decentralised (national) level** for the others.

Proposed way forward:

On this point there is **no possibility for compromise**. The option to transfer the responsibility for the assessment of the safety and performance of medical devices from notified bodies to a regulatory authority and to replace the CE marking by a marketing authorisation, such as exists in the field of pharmaceuticals, was discarded in the impact assessment as inappropriate for the sector. It would be **detrimental to innovation and to the competitiveness** of the European medical device sector, **without any demonstrated added value for patient safety**. A *centralised* marketing authorisation would have a significant impact in terms of **time to market and costs** for regulatory compliance. This would ultimately deprive patients of innovative medical devices and increase healthcare costs. A *decentralised* marketing authorisation would have in addition a **negative impact on the internal market** for medical devices as it would allow a Member State to refuse a device authorised by another Member State access to its market because it considers it does not ensure an appropriate level of protection of health and safety. Moreover, certain parameters need to be kept in mind if such a fundamental change were to be considered: **significant resources** would be required both at national and at EU level (Commission's services and EMA).

IMCO Committee:

The Rapporteur proposes changes to the proposed scrutiny procedure: instead of an examination of selected files for high-risk devices, control by the MDCG should be **systematic for implantable devices in class III**. No provision is made for control of other class III devices. The MDCG, assisted by a **Scientific Advisory Board** managing expert panels, would then have to deliver a scientific assessment within 45 days. The opinion of the MDCG would be **binding** on the notified body.

Proposed way forward:

In principle, **we are not opposed to an approach which aims at reinforcing the control mechanism proposed**. However, some **random control** of non-implantable class III devices needs to be maintained. Moreover, since the MDCG does not have a legal personality, it is not clear who would be **legally responsible** in case the manufacturer wants to challenge the notified body's refusal to deliver the certificate and even sue for damages in case of loss of earnings. In addition, the creation of a Scientific Advisory Board and expert panels would **duplicate the work of the Scientific Committees** and generate **risks in terms of independency**.

- **Reprocessing of medical devices**

According to the Commission proposal, reprocessors of single-use devices are considered as manufacturers and have to comply with all the requirements of the Regulation. Member States willing to prohibit the reprocessing of single-use devices on their territory and/or the placing on their market of reprocessed devices are allowed to do so.

ENVI Committee:

The Rapporteur proposes a system according to which **all devices would be labelled as reusable**; by derogation, manufacturers would be granted the possibility to label them as single-use if they provide **justification** based on sufficient scientific evidence. For

manufacturers of class III devices, this justification would be controlled by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). A reprocessor who would like to challenge the single-use label of a manufacturer would have to provide evidence that the medical device can be reprocessed safely and to obtain a positive opinion from the SCENIHR.

Proposed way forward:

The proposed system **does not seem to be practically feasible**. The systematic involvement of the SCENIHR before labelling class III medical devices as single-use would severely delay their placing on the market, thus undermining patient access and industry capacities.

IMCO Committee:

The Rapporteur suggests distinguishing between single-use devices (devices which have been tested and demonstrated to be impossible to reuse), intended single-use devices (devices intended for single-use for which impossibility of reuse have not been demonstrated) and multiple-use devices (devices which are reusable and for which the manufacturer must indicate the necessary processes to allow reuse and a limit on the number of reuses). Reprocessing would be allowed in the case of intended for single-use devices but not for single-use devices and would be regulated under the same conditions as proposed by the Commission.

Proposed way forward:

We consider that this proposal **might be accepted**, as it **goes in the same direction as our proposal**, but **clarifies** that the rules on reprocessing may only apply to "intended single-use devices" and not to the devices which have been demonstrated as impossible to reuse.

- **Extension of the scope of the legislation to devices for aesthetic purposes**

IMCO Committee:

The Commission proposal extends the scope of the legislation to cover certain implantable or other invasive products without medical purpose (*e.g.* dermal fillers, breast implants, contact lenses) by means of a positive list. The Rapporteur considers that this list could be too restrictive and does not reflect the actual situation on the market. She has therefore suggested the inclusion of a definition of "aesthetic assimilated device" rather than a positive list which would need to be amended to keep pace with technological and scientific progress.

Proposed way forward:

We consider that **the best approach is the positive list**. It would be difficult for a definition to be sufficiently precise on the appropriate scope and avoid grey areas. For example, the suggested definition would cover "aesthetic" tattoos which may not be appropriately regulated as medical devices but would exclude liposuction equipment which should be covered due to the risk they represent.

- **Risk classification of devices composed of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body**

ENVI Committee:

The Rapporteur considers that the rule classifying the abovementioned devices in the highest risk class (class III) is disproportionate and **should be deleted.**

Proposed way forward:

We cannot accept this amendment. This rule addresses an important public health issue: some of the products intended to be ingested, inhaled or administered rectally or vaginally, such as osmotic laxatives or fat absorbers, may be qualified as medical devices. These products present some important risks that the current legislation does not address (such as interactions with medicinal products and toxicity) and no existing classification rule is adapted to these products. Rule 21 classifies these devices in the highest risk class, ensuring thereby that they are subject to the most stringent control. If needed, the Commission can reclassify some of these devices by a delegated act, in cases where a lower class would be more adapted. A **compromise solution** could consist in further specifying the rule to avoid covering low risk consumer products which are not *primarily* intended to be ingested or inhaled (*e.g. medical toothpaste*). In addition, a classification in class IIb could be envisaged for devices that are not systemically absorbed (*e.g. activated coal, insoluble fibres, insoluble fat absorbents*), while devices systemically absorbed would remain in class III (*e.g. antacid*). A compromise seems to emerge in this direction in the Council Working Party.

- **Clinical investigations**

ENVI Committee:

The Rapporteur proposes the reintroduction of independent **ethics committees** and the use of **randomized controlled clinical investigations**.

Proposed way forward:

While some technical aspects will need to be further checked (*e.g.* the applicability of the concept of "randomized" controlled clinical investigations to medical devices for which no placebo can be used as it is done in the medicinal field), overall **we can support the proposed amendments as far as we ensure convergence with the proposal for a Regulation on clinical trials** which is also currently in negotiation.

- **Compulsory liability insurance**

IMCO Committee:

The Rapporteur has introduced provisions on **compulsory liability insurance** for manufacturers of medical devices, where a device causes death or injury to the patient(s) or user(s).

Proposed way forward:

This is a good suggestion and we have prepared a note to the **Legal Service** to confirm EU competence to act on that matter. Similar provisions exist in the area of clinical trials for pharmaceuticals.

2. Proposal on *in vitro* diagnostic medical devices

The **main amendments** on this proposal are contained in the report of the Rapporteur of the **ENVI Committee.**

- **Restrictions on the use of genetic tests, informed consent and genetic counselling**

The Rapporteur proposes to add provisions **restricting the use** of genetic tests **to health professionals**, as well as requirements on **counselling** and **informed consent** in case of genetic tests.

Proposed way forward:

In principle, **we can agree** with the proposals of the Rapporteur subject to confirmation by the **Legal Service** regarding EU competence in this matter.

- **Clarification of the scope of the proposal with regard to lifestyle tests**

The Rapporteur proposes to further clarify the scope of the IVD proposal in particular with regard to **lifestyle tests** which pursue an indirect medical purpose (*e.g.* genetic test to define the most appropriate diet to avoid obesity).

Proposed way forward:

In principle, **we could agree** with this proposal but would like to suggest further technical amendments to the definition of 'Medical Device'.

- **Derogation for in-house tests**

The current Directive exempts so-called in house tests (*i.e.* tests manufactured and used within a single health institution) from the application of its requirements. The proposal foresees to keep this derogation for Class A, B and C, but Class D is subject to most of the requirements of the proposed Regulation. The Rapporteur proposes that **in addition to Class D in-house tests, in-house companion diagnostics** (used to predict the response or the reaction of a patient to a specific treatment and which are classified as Class C) shall be submitted to most of the requirements of the proposed Regulation.

Proposed way forward:

We **can agree** with the Rapporteur to submit companion diagnostics manufactured and used within a single heath institution to most of the requirements foreseen in the Regulation.

- **Transitional period and advanced application of some provisions**

The Rapporteur proposes that the transitional period to register economic operators, devices and certificates in the electronic system (Eudamed) be **deleted** arguing that the system should be operational as soon as possible, whereas the Commission proposes a transitional period of 18 months after the date of application of the IVD Regulation during which the registration would be voluntary. The Rapporteur proposes that some other provisions of the Regulation **become applicable earlier**, as a matter of urgency to improve the system.

Proposed way forward:

We can accept to shorten the transitional period but it is essential, in order to ensure a smooth application of the registration system, to **maintain the period of 18 months** during which the registration of economic operators, devices and certificates would be voluntary. This period could start when the EUDAMED modules will be available (*i.e.* 3 years after entry into force and not 5 years as mentioned in the proposal). Concerning the earlier application of other provisions (*e.g.* vigilance), we do not oppose the principle **as long as the necessary tools for their implementation (*e.g.* EUDAMED) are ready**.

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c.c.: CAB BORG CAD (ve_ca.16.cad), Ms J. Darmanin, Mr N. Behrndt, Mr M. Seychell, Mr M. Hudson, Ms D. Spanou, [redacted]